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OPP-2003-0122-

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

September 29, 2003

Memorandum

To: OPP Docket, Re: OPP-2003-0122

From: Jackie Mosby, Acting Branch Chief
Special Review and Reregistration Division

Subject: Fenthion Comments from the Lee County Mosquito Control District

The Lee County Mosquito Control District submitted comments to the Agency on August 15, 2003, regarding the voluntary cancellation of fenthion. These comments were submitted to docket number OPP-2002-0193; however, the submitter has indicated that it is also appropriate to include them in docket OPP-2003-0122. Accordingly, this set of comments should be placed in OPP-2003-0122.

LEE COUNTY MOSQUITO CONTROL DISTRICT

877-844-2174
239-694-2174
SUNCOM 725-1011
FAX 239-693-5011
POST OFFICE BOX 60005
FORT MYERS, FLORIDA 33906
WWW.LCMCD.ORG

WILLIAM R. OPP, DIRECTOR

August 15, 2003

Mr. James A. Hollins
Information Resources Services Division (7502C)
Office of Pesticide Programs
U. S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, DC 20460-0001

Dear Mr. Hollins:

The Lee County Mosquito Control District, Fort Myers, Florida submits the following comments to the official public docket [OPP-2003-0193;FRL-7310-3] within the Public Information and Records Integrity Branch (PIRIB); Room 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, Virginia.

In response to the Federal Register Notice (Volume 68, No. 118, 19 June 2003) RE: "Notice of Receipt of Requests to Voluntarily Cancel Certain Pesticide Registrations", the Lee County Mosquito Control District will restrict its comments relative to the EPA Registration Number 432-1285 (Baytex Liquid Concentrate Insecticide), Bayer Environmental Science.

Pursuant to carrying out public health vector control programs within the State of Florida, mosquito control districts particularly those situated in southern Florida, have relied upon the availability of Fenthion for control of adult mosquitoes. Consequently, we are interested in the continued registration of Fenthion for public health vector control. Mosquitoes can be a significant nuisance affecting lifestyles and quality of life, as well as serving as vectors for a number of diseases affecting both humans and domestic and wild animals. Public health officials are very close to "no alternative pesticides available' for the control of adult mosquitoes. Consequently, without any new chemistry forthcoming, we must remain good stewards of the few remaining "tools" in the toolbox such as Fenthion.

There is substantial reliable evidence that confirms that, when used in accordance with label directions, Fenthion can be used for vector control without generally causing unreasonable adverse effects to man or the environment, including birds.

The Lee County Mosquito Control District, Fort Myers, Florida has been applying Fenthion for adult mosquito control since July 2, 1965, without any adverse effects to the environment, including birds. This is not attributable to simply "good luck" alone. According to the U. S. Fish and Wildlife Service, the J. N. "Ding" Darling National Wildlife Refuge located on Sanibel Island, Florida receives over 800,000 visitors per year - the second highest visited National Wildlife Refuge within the U. S. If Fenthion use in vector control operations around the refuge was creating a problem such as causing bird kills, then the mosquito control district and the stewards of the Refuge, namely Fish and Wildlife Service, would certainly be made aware of such problems.

When fenthion is applied as stated on the label for adult mosquito control, application rates may vary between 25 to 71 times less the rates that it would take to kill birds (According to the Quelatox® label). Unless a malfunction occurs within the spray system or the Federal Pesticide Label is not followed then one would expect to have an established safety record similar to the one exhibited by the Lee County Mosquito Control District for the past 38 years. Additionally, enclosed is a letter addressed to George Wichterman, Entomologist with the Lee County Mosquito Control District and signed by Mr. Louis Hinds, the former manager of the J. N. "Ding" Darling National Wildlife Refuge which clearly states that for more than ten years, use of Fenthion around or adjacent to the Refuge has not resulted in any birds kills.

According to a letter recently addressed to EPA by the U. S. Department of Interior states "Fenthion is unnecessary for adult mosquito control because often equally efficacious products are available." This is totally incorrect. There are very few "tools" that public health vector control specialists currently have available for adult mosquito control. The first two products available in Florida are organophosphates products Dibrom (Naled) and Fenthion (Baytex) which are equally efficacious for public health vector control. To avoid resistance problems, use of both products should follow the appropriate rotation of chemicals. However, the remaining 48 states do **not** have this capability for resistance management through rotation of these two public health pesticide products. They rely principally on Dibrom and several synthetic pyrethroids. According to Centers for Disease Control and Prevention (CDC) records, thirteen states have recorded pest resistance to these very synthetic pyrethroids used in public health vector control. The synthetic pyrethroid class of compounds includes Resmethrin and Sumithrin. Unfortunately, both of these products are unreliable in large scale settings due to changes occurring in the estuarine environment producing inconsistent results. In a vector control operation, a public health specialist does not have the luxury to repeat applications of a pesticide over a predetermined area because a product may not be dependable.

Another public health pesticide product labeled for adult mosquito control is Malathion. Throughout South Florida, salt marsh adult mosquitoes have developed resistance to this product. This was confirmed by the USDA during the 1960's. To date, this product is still unusable for salt marsh mosquitoes.

Other potential alternative pesticide products for vector control are the natural pyrethrins. Due to the limited supply of natural pyrethrins from Kenya, Africa, most of the 900 Mosquito Abatement Districts throughout the United States are unable to obtain a sufficient quantity of product to conduct adult mosquito control operations due in large part to a rationing of product by the purveyor. Many of these abatement districts are located in coastal areas of the United States, e.g. Eastern Seaboard, Gulf Coast and the Pacific Coast localities. Consequently, because there is a potential for harmful effects to non-target beneficial insects within the estuarine area, the natural pyrethrins are an unusable tool for public health vector control within these same estuarine areas.

The only other remaining public health pesticide product is the synthetic pyrethroid-Permethrin. Currently, the State of Florida will not allow its use in aerial mosquito control programs because of the potential adverse effects to its estuarine environment. As a result, only ground operations are permitted. Because many treatment areas are inaccessible to land-based vehicles, public health vector control specialists are precluded from making an effective application with Permethrin.

In summary, mosquito abatement personnel in Florida have only two completely reliable, efficacious public health pesticide products - Dibrom (Naled) and Fenthion (Baytex). The remaining 48 states do not have this option. Without Fenthion, Dibrom would be the only remaining effective "tool in the tool box" for consistent control of adult mosquitoes. It is clear that relying on one chemical will likely lead to resistance problems. Within the other abatement districts which are only using Dibrom (Naled) as their sole line of defense against public health vectors, Directors of these operations remain cognizant that biological selection for tolerance to the chemical is **not** on their side. In other words, reliance on Dibrom in the short term may be sufficient; however, long term this option remains unwise. EPA officials have recognized that public health officials are currently utilizing older chemicals for public health vector control, without the availability of new chemistry forthcoming. As a result, public health officials need to preserve existing products and rotate chemicals whenever possible.

Concomitant with issues affecting the public health vector control community is the prevailing attitude within the Department of Health and Human Services (CDC) as stipulated under the Food Quality Protection Act, 1996 (FQPA), "upon timely request by the registrant or any other interested person, or on the Administrator's own initiative may, consult the Secretary (DHHS) prior to taking final action to suspend registration under section 4, 6 (e), or 6(f)." This provision of FQPA, 1996, has been undertaken as prescribed and expressed at a public meeting with EPA and interested stakeholders in Orlando, Florida during January, 2001 (see attachment).A designate from DHHS (CDC) Dr. Duane Gubler, Chief of the Division of Vector-Borne Infectious Diseases section at CDC, Fort Collins, Colorado, stated that, "loss of any single compound used for public health purposes, therefore, seriously compromises our ability to prevent and control vector-borne disease in this country." He further states "with the potential for geographic spread of West Nile Virus in this country, however, it is likely that more public health jurisdictions will request registration of fenthion for use in their areas." Dr. Gubler also expresses his opinion on insecticide resistance already

iterated by the Lee County Mosquito Control District in the aforesaid paragraph. "Fenthion is critical for insecticide resistance management in areas where repeated mosquito control is necessary. Without this compound, resistance to other insecticides will likely develop at a much faster rate."He also states Fenthion is well accepted by the public in those areas where it is routinely used."

And he acknowledges the public's acceptance of Fenthion's use for adult mosquito control with the following statement, "Fenthion is well accepted by the public in those areas where it is routinely used". With the "dramatic resurgence of infectious diseases in general" CDC officials point out the need to "maintain all currently available tools to fight those diseases until new and more effective alternatives can be developed." As of this writing (January, 2001) CDC had "documented the introduction, establishment and spread of two new exotic vector-borne diseases in the country: West Nile and Leishmaniasis, These will not likely be the last."

Most importantly CDC concludes its comments with the take home message that all available public health pesticide products will be needed to prevent and control epidemics just mentioned. As Dr. Gubler's final submission states " It is my view that the benefits of fenthion far outweigh the risks."

What has been most frustrating as a stakeholder and an end-user of this product for the control of adult mosquitoes for the past 38 years in Southwest Florida, involves the process of reregistration developed by EPA and followed by the registrant Bayer Corporation.

During September, 2000, an Interim Reregistration Eligibility Decision (IRED) document was published by EPA on Fenthion. Critical to maintaining this registration involved a series of Data Call Ins (DCI) requiring data to be submitted by the registrant (Bayer Corporation) . Within the document are three general data issues which EPA addressed: Developmental Neurotoxicity Studies, Ecotoxicity studies, and Worker Exposure studies. However, the story of these data requirements is perplexing. Additional data requirements per se were in the (IRED) issued for fenthion in early 2001 (Attachment (page from IRED document)). Discrepancy exists between what EPA has published in the IRED and on what has been actually requested by the Agency.

Following are the three general data issues to be addressed and the evolution of each:

1). Developmental Neurotoxicity Studies
EPA issued a Data Call-In for developmental neurotoxicity studies of all OP's registered for food uses in 1999. Fenthion was included in that DCI as at that time Bayer Corporation still had registered products for use on livestock. In subsequent discussions with the Agency, it was agreed that if food uses were cancelled, then the DCI would not be applicable as the only use pattern indicated in the DCI was for food uses. Bayer Corporation went on to cancel all its Tiguvon products for swine and cattle and the tolerances were revoked. However, when EPA issued the IRED they referenced this DCI and indicated it was applicable to fenthion due to residential exposure. Consequently, no DCI for the DNT was included with the IRED itself. In

April of 2001, Bayer Corporation received a letter from Ms.Lois Rossi, Division Director of Special Review and Reregistration, inquiring what was Bayer's intent for addressing the DNT requirement. Bayer Corporation responded with a letter (attached) indicating that Bayer Corporation did not believe the 1999 DCI was applicable nor were data necessary for fenthion and but should the Agency go on to require it, then Bayer could not justify the cost of the study and the Agency would need to consult with the U.S. Dept. of Health and Human Services (DHHS) to determine if funding would be provided in accordance with Section 4(n) of FIFRA. **No** official response was ever received from the Agency, **nor** a new DCI. issued.

2). Ecotoxicity Studies
In the IRED, the EPA noted some data gaps for fenthion, specifically the two avian reproduction studies and three acute toxicity studies for mysid shrimp. However, in the DCI issued with the IRED (attached) none of these data were included. No DCI for these data was ever issued, thus the Agency technically never actually required them; however, in the more recent discussions EPA indicated that the avian data in particular were the data they wanted to obtain. This latter request occurred after the alleged bird kills in Collier County, Florida.

3). Worker Exposure Studies
EPA also indicated in the IRED that they intended to issue "in the near future" a DCI for worker exposure data for all mosquito pesticides. **No** DCI has been issued to date. The only generic data call in requirement for fenthion issued with the IRED was for worker exposure associated with filling perches, applicable to the avicide use which Bayer Corporation no longer supported. Bayer Corporation indicated as such to the Agency.

From a legal aspect, there were no data requirements on which the Agency could have pursued action to cancel or suspend fenthion under either FIFRA Section 4(f) or 6(b), except if EPA did so based on a determination that even when used properly there were unreasonable adverse effects on the environment. An action on this basis would have triggered a risk benefit determination and consultation with DHHS, which Bayer Corporation had no indication that was EPA's intent. As a result, Bayer Corporation's position had been that they had no economic stake in the product and could not justify any expenditures, but would continue to provide it as a public health pesticide until some action was taken.

As a stakeholder (end user of the public health pesticide product)I respectfully submit to you how may EPA proceed with this voluntary request for cancellation of fenthion when substantive questions still exist not only on what data are actually required, if any, by the registrant in order to comply with the IRED, but also why the Administrator of EPA has not requested the DHHS (who has already expressed its support for fenthion on the required consultation basis mandated under "Section 4" (n) (2) Consultation. Funds to Develop Public Health Data" and require the

public support through federal funding the data needed to continue this reregistration of a necessary public health pesticide for mosquito control.

In conclusion, according to a Federal Register Notice, "Bayer stated that this decision was based on the fact that the market for this product is very limited, in addition to the expected costs for generating data to meet the requirements mandated by the FIFRA reregistration process". In light of what was iterated in the preceding paragraph and also based upon the recommendation of the Department of Health and Human Services (CDC)on retaining this valued public health pesticide product, the Lee County Mosquito Control District requests the Agency to consider a withdrawal of the notice to cancel the "notice of receipt of requests to voluntarily cancel certain pesticide registrations" in accordance with Section 6(f)(1) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended.

Sincerely,

Mr. William R. Opp
Director

WRO/jk

Enclosures

7-25

Summary of Comments by Dr. Duane J. Gubler at the Fenthion Stakeholder's Meeting, Orlando, Florida

January 17, 2001

First, I want to thank EPA for the opportunity to attend this meeting and make comments on the benefits of fenthion on behalf of CDC.

An important fact to keep in mind as we weigh the risks and benefits of all public health pesticides, is that we have very few of these available to us for current use in our efforts to control mosquitoes and other arthropods that transmit vector-borne disease, and that there are no new public health pesticides in the pipeline for approval. Loss of any single compound used for public health purposes, therefore, seriously compromises our ability to prevent and control vector-borne diseases in this country.

Fenthion has had only limited use in the U. S. during the past 20 years when vector-borne disease activity has been low because it is expensive and considered controversial by many decision makers. With the potential for geographic spread of West Nile virus in this country, however, it is likely that more public health jurisdictions will request registration of fenthion for use in their area. Some of the specific benefits of using fenthion are as follows:

1. It is effective as an adulticide and larvicide against a wide variety of mosquito species. This is important because WN virus has already been isolated from 14 species of mosquitoes belonging to six genera in this country, and it is likely that as WN virus becomes established in new

geographic locations, it will develop unique focal transmission cycles that must be controlled.

2. Fenthion is critical for insecticide resistance management in areas where repeated mosquito control is necessary. Without this compound, resistance to other insecticides will likely develop at a much faster rate.

3. Fenthion is less corrosive than alternative insecticides such as naled and malathion.

4. Fenthion can be used at a lower rate than malathion, making it possible to treat larger areas with a single load, and therefore, reducing exposure to loaders.

5. Fenthion is compatible with other control methods.

6. Fenthion is well accepted by the public in those areas where it is routinely used.

The dramatic resurgence of infectious diseases in general, and vector-borne diseases in particular, in the past 20 years has underscored our vulnerability to epidemics of these diseases, and has reinforced the need to maintain all currently available tools to fight these diseases until new and more effective alternatives can be developed. In recent years, we have documented increased frequency of the introduction of diseases such as malaria, dengue and yellow fever, and local transmission of dengue and malaria. We have documented the introduction and spread of three exotic mosquito species that are efficient disease vectors: *Aedes albopictus*, *Ochlerotatus* (formerly *Aedes) togoi*, and *Ochlerotatus* (formerly *Aedes*) japonicus. In just the past two years,

we have documented the introduction, establishment, and spread of two new exotic vector-borne diseases in this country: West Nile virus and Leishmaniasis. These will not likely be the last.

West Nile virus perhaps poses the greatest threat for widespread geographic distribution in this country. As noted above, it has already been isolated from 14 mosquito species, and has been documented as causing high morbidity and mortality in 79 species of birds (68 native and 11 exotic), horses, cats, bats (3 species), squirrels, skunks, rabbits, raccoons, and humans. We will need all available public health pesticides in order to effectively prevent and control epidemics of this disease. It is my view that the benefits of fenthion far out weight the risks.

VI. What Registrants Need to Do

A. Manufacturing Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of fenthion for the above eligible uses has been reviewed and determined to be substantially complete. The following data gaps remain:

Avian reproduction studies with the northern bobwhite and the mallard are required. Three acute toxicity studies with the mysid shrimp are required: 1 using a formulation, 1 using the sulfoxide degradate, and 1 using the sulfone degradate.

A mosquito pesticide worker exposure DCI will be issued in the near future for all mosquito pesticides. This DCI will also include post-application bystander data requirements such as deposition studies and turf transferrable residue studies.

Also, a Data Call-In Notice (DCI) was recently sent to registrants of organophosphate pesticides currently registered under FIFRA (August 6, 1999 64FR42945-42947, August 18 64FR44922-44923). DCI requirements included acute, subchronic, and developmental neurotoxicity studies; due dates are 9/2001. The developmental neurotoxicity study is required for fenthion because it is used as a wide area mosquito adulticide which results in residential exposure.

2. Labeling for Manufacturing Use Products

Because the Agency intends to hold a public stakeholder meeting to determine the best ways to reduce risks associated with the use of fenthion, the registrant does not need to submit applications for amended registration at this time.

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then the study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

COMPOUND: Fenthion Generic Data Call-In

FLASHER NO. **3078**

PENDING FLASHER SCHEDULE

FLASHER RECEIPT	ACTION DESCRIPTION	DATA REQUIREMENTS	EPA GUN	SECTION	SUBMIT DATE	COMMENTS
1/16/01 (1/23/01)	Generic Data call-in	90-Day Response			4/23/01	
		Estimation of Dermal Exposure	231	Product Safety	1/23/02	

General Comments: This flasher is being issued based on the Fenthion IRED.

January 24, 2001

United States Environmental Protection Agency
Washington, D.C. 20460

DATA CALL-IN RESPONSE

Form Approved
OMB No. 2070-0107
2070-0057
Approval Expires 12/31/00

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form.
Use additional sheet(s) if necessary

1. Company name and Address	2. Case # and Name	3. Date and Type of DCI
003125 BAYER CORP AGRICULTURE DIVISION 8400 HAWTHORN RD BOX 4913 KANSAS CITY MO 64120	0290 Fenthion Chemical # and Name 053301 Fenthion	GENERIC

4. EPA Product Registration	5. I wish to cancel this product registration voluntarily	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	6b. I agree to satisfy Generic Data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is an MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
3125-148 3125-197					

8. Certification

I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative_____

9. Date

10. Name of Company Contact

11. Phone Number

United States Environmental Protection Agency
Washington, D.C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved
OMB No. 2070-0107
2070-0057
Approval Expires 12/31/00

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary

1. Company name and Address 003125
BAYER CORP
AGRICULTURE DIVISION
8400 HAWTHORN RD BOX 4913
KANSAS CITY MO 64120

2. Case # and Name
0290 Fenthion
Chemical # and Name 053301
Fenthion

3. Date and Type of DCI
GENERIC

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
231 *	Estimation of Dermal Exposure at Outd							12 mos.	

10. Certification
I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.
Signature and Title of Company's Authorized Representative_____

11. Date

12. Name of Company Contact

13. Phone Number

United States Environmental Protection Agency
Washington, D.C. 20460

*** COMMENTS FOR GUIDELINE REQUIREMENTS**

Case # and Name
0290 Fenthion
Chemical # and Name
053301 Fenthion

GUIDELINE	COMMENT
231	Dermal exposure of worker while filling/refilling perch. Please refer to subdivision U of the Pesticide Assessment Guidelines for more information on the requirements of this study.

List of All Registrants Sent This Data Call-In Notice

Case # and Name
0290 Fenthion
Chemical # and Name
053301 Dimethyl O-(4-(methylthio)-m-tolyl) phosphorothioa

Company Number	Company Name	Additional Name	Address	City & State	Zip
003125	BAYER CORP	AGRICULTURE DIVISION	8400 HAWTHORN RD BOX 4913	KANSAS CITY MO	64120
011556	BAYER CORP	AGRICULTURE DIVISION, ANIMAL HEALT	BOX 390	SHAWNEE MISSION KS	66201

United States Environmental Protection Agency
Washington, D. C. 20460

LIST OF ALL REGISTRANTS SENT THIS DATA CALL-IN NOTICE

Case # and Name: 0290 Fenthion

Co. Nr.	Company Name	Additional Name	Address	City & State	Zip
003125	BAYER CORP	AGRICULTURE DIVISION	8400 HAWTHORN RD BOX 4913	KANSAS CITY MO	64120
005481	AMVAC CHEMICAL CORP	ATTN: JON C. WOOD	4695 MACARTHUR COURT, SUITE 1250	NEWPORT BEACH CA	92660
011556	BAYER CORP	AGRICULTURE DIVISION, ANIMAL HEALT	BOX 390	SHAWNEE MISSION KS	66201
067858	FLORIDA TROPICAL FISH FARMS ASSN,		BOX 1519	WINTER HAVEN FL	33882
071649	ARKANSAS BAIT AND ORNANMENTAL FISH		1131 BROWNSVILL LOOP	LONOKE AR	72086
072871	MISSOURI AQUACULTURE ASSOCIATION		P.O. BOX 630	JEFFERSON CITY MO	65102

RF

Bayer

Bayer Corporation
1275 Pennsylvania Ave, N.W.
Suite 801
Washington, D.C. 20004
Phone 202 737-8900
Fax: 202 737-8909

May 1, 2001

Ms. Lois Rossi, Director
Special Review and Reregistration Division (H7508W)
Office of Pesticide Program
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, D.C. 20406

Subject: **Fenthion, Case 0209**
Response to Agency Letter Dated April 23, 2001
Developmental Neurotoxicity Testing Data Call-In

Dear Ms. Rossi:

Bayer Corporation is responding to your letter dated April 23, 2001, regarding the Developmental Neurotoxicity (DNT) Study Data Call-In for fenthion issued by the Agency September 10, 1999. In your letter you indicate that Bayer had not responded to the Data Call-In with submission of the *Data Call-In Response Form* and the *Requirement Status and Registrant Response Form.* However, Bayer did submit these responses to the data call-in with a letter dated December 20, 1999. In that letter Bayer cited its existing neurotoxicity data for fenthion and referenced another letter (J. Thornton to L. Rossi, December 17, 1999) in which Bayer addressed the DNT requirement for a number of Bayer products. Bayer indicated agreement to conduct the DNT studies if outstanding technical issues could be resolved and scheduling agreed upon. Copies of both letters and Bayer's Data Call-In Response and Registrant Response forms for fenthion, submitted December, 1999 are attached for reference. However, please note that on the fenthion DCI received by Bayer in 1999 the only use pattern indicated in the DCI as subject to the requirement were food uses (see column 6, "Use Pattern" on the Registrant's Response form). It was this designation that led to Bayer's subsequent discussions with the Agency regarding the possibility of canceling all food uses of fenthion (livestock) to aver this data requirement. It was conveyed to Bayer by the Agency that should Bayer elect to cancel the food uses, the data requirement would be dismissed. Bayer proceeded to voluntarily take such action and all livestock uses were canceled effective 12/31/2000.

But the Agency later determined that DNT studies were likewise needed for products with residential uses and/or exposure when Bayer queried the Agency with regard to the DNT data requirement for trichlorfon, another organophosphate product registered for use on residential lawns. However, a new or revised DCI for fenthion prescribing the requirement of a DNT for the mosquito adulticide use pattern was never received by Bayer, nor was a DNT study requirement included in the generic DCI for fenthion issued with the IRED released earlier this year. Nevertheless, Bayer has been aware of the Agency's desire to have a DNT study for fenthion and has indicated to the Agency in a number of occasions that with the deletion of all uses of fenthion except for the mosquito adulticide use in Florida, the conduct of a DNT study cannot be economically justified for fenthion. We have also conveyed that since this is a public health use, that the Agency and the Department of Health and Human Services (DHHS) could deem its use of such significance as for DHHS to fund the data necessary to support its continued registration, in accordance with FIFRA Sec. 4(n).

This point was also made in Bayer's December 2000 letter to the Agency outlining its schedule for the conduct of DNT studies for its products and again in a electronic mail correspondence from myself to Ms. Tracy Lindley (nee Truesdale) of SRRD on March 3, 2001. Bayer has stated that we felt the risk associated with the use of fenthion did not warrant the requirement for a DNT and have made it known that sales volume of this compound for mosquito use would not bear the cost of the study should the Agency require it. Fenthion remains on Bayer's test schedule only for the purposes of scheduling if it is determined by the Agency that the study is necessary to maintain the registration of fenthion for as a mosquito adulticide and alternative funding under FIFRA Sec. 4(n) can be secured. Under the current schedule, for which a response from the Agency as to its acceptability has been projected for May 25, 2001, the DNT study for fenthion is slated to begin January 2004. Thus, the option of obtaining funding support per FIFRA Sec. 4(n) is still a viable option, should the EPA and DHHS determine that the benefits of the use of fenthion in public health protection are of such significance as to warrant it.

While the users of fenthion (Baytex) have stressed their need for the continued availability of this product (which we have agreed to continue to provide), the very limited use and market for this product makes it difficult for Bayer to continue to support. Therefore, we also would invite the opportunity to investigate possible options for the product registration in the United States, one which might be transfer of the registration of the Baytex registration to the Centers for Disease Control (CDC) of DHHS. Given the uncertain future of the need for mosquito control in the U.S. and particularly in Florida with the predication of West Nile Virus becoming endemic there, the CDC has indicated that it would like to see all available mosquito control tools be maintained.

I invite the opportunity to further discuss the future of Baytex (fenthion) with you. Please contact me at (202) 756-3775 if you would like to discuss these possible options and what may be done to maintain the use of fenthion for the protection of public health as a mosquito adulticide.

Sincerely,

BAYER CORPORATION
AGRICULTURE DIVISION

Julie M. Spagnoli
Manager
Federal Regulatory Affairs

Attachments

c: Tracy Lindley, SRRD (H7508W)

Bayer

Agriculture Division

December 20, 1999

Karen Angulo
Special Review and Reregistration Division (7508C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

Subject: Neurotoxicity Data Call-In Notice
Chemical Name: Fenthion
Case Number: 0290
Chemical Number: 53301

Dear Ms. Angulo:

Enclosed are the Data Call-In Response and Requirements Status Registrant's Response forms for the subject product.

On the Requirements Status and Registrant's Response form, we have indicated for the acute and subchonic neurotox screening battery that we are citing an existing studies. Below are the MRID Nos. and the Agency's classificatcn.

Study Title	MRID Number	Agency Classification
Neurotox Screening Battery (Acute)	44326401	Acceptable
Neurotox Screening Battery (Subchronic)	44339401	Acceptable

For the developmental neurotoxicity study, Bayer has submitted a letter to Lois Rossi (copy enclosed) outlining Bayers plans to supply developmental neurotoxicity studies for Bayers compounds.

If you have any questions concerning this submission, please contact Mr. Charles Boyd of my staff at (816) 242-2457.

Sincerely,
Bayer Corporation
Agriculture Division

John S. Thornton
Director, Product Registrations
and Regulatory Affairs

JST:CWB

Enclosures

United States Environmental Protection Agency
Washington, D.C. 20460

REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE

Form Approved
OMB No. 2070-0107
2070-0057
Approval Expires 12/31/99

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary

1. Company name and Address 003125
BAYER CORP
AGRICULTURE DIVISION
8400 HAWTHORN RD BOX 4913
KANSAS CITY MO 64120

2. Case # and Name
0290 Fenthion
Chemical # and Name 053301
Fenthion

3. Date and Type of DCI
GENERIC

4. Guideline Requirement Number	5. Study Title	PROTOCOL	Progress Reports 1	2	3	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
870.6200 *	Neurotox Screening Battery (Acute Stu					A	TGAI/PAI	12 mos.	f
870.6200 *	Neurotox Screening Battery (Subchroni					A	TGAI/PAI	12 mos.	f
870.6300 *	Developmental Neurotoxicity Study		Y			A	TGAI/PAI	24 mos. *	a*
	protocol	Y						4 mos. *	a*

* See attached letter concerning timing of protocol and DNT study submissions

10. Certification
I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.
Signature and Title of Company's Authorized Representative

11. Date
December 20, 1999

12. Name of Company Contact
John S. Thornton, Director, Product Registrations and Regulatory Affairs

13. Phone Number
(816) 242-2255

United States Environmental Protection Agency
Washington, D.C. 20460

DATA CALL-IN RESPONSE

Form Approved
OMB No. 2070-0107
2070-0057
Approval Expires 12/31/99

1. Company name and Address 003125
BAYER CORP
AGRICULTURE DIVISION
8400 HAWTHORN RD BOX 4913
KANSAS

2. Case # and Name
0290 **Fenthion**
Chemical # and Name 053301
Fenthion

3. Date and Type of DCI
GENERIC

4. EPA Product Registration	5. I wish to cancel this product registration voluntarily	6. Generic Data		7. Product Specific Data	
		6a. I am claiming a Generic Data Exemption because I obtain the active ingredient from the source EPA registration number listed below.	b. I agree to satisfy Generic data requirements as indicated on the attached form entitled "Requirements Status and Registrant's Response."	7a. My product is an MUP and I agree to satisfy the MUP requirements on the attached form entitled "Requirements Status and Registrant's Response."	7b. My product is an EUP and I agree to satisfy the EUP requirements on the attached form entitled "Requirements Status and Registrant's Response."
3125-148			X		
3125-197			X		
MO99000300			X		

8. Certification
I certify that the statements made on this form and all attachments are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine, imprisonment or both under applicable law.

Signature and Title of Company's Authorized Representative for JST

9. Date
December 20, 1999

10. Name of Company Contact
John S. Thornton, Director, Product Registrations and Regulatory Affairs

11. Phone Number
(816) 242-2255

Bayer

Agriculture Division

December 17, 1999

Ms. Lois Rossi
Special Review and Reregistration Division (7508C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

Subject: **Neurotoxicity Data Call-In Notices for BAYER Organophosphate Pesticides**

Dear Ms. Rossi,

Sent under separate cover, to the attention of Ms. Karen Angulo, BAYER has submitted its responses to the recently received Data Call-In (DCI) Notice for neurotoxicity. As you are aware, BAYER has already submitted, for all its Organophosphate (OP) pesticides except tribuphos, well in advance of this DCI, studies to measure the acute and subchronic neurotoxic behavior of our chemicals. Specifics as to those studies are listed below:

Chemical name	Chemical number	Acute Testing / MRID	Subchronic Testing / MRID
azinphos-methyl	58001	106365 / 43360301	106839 / 43826601
coumaphos	36501	104961 / 44544801	105016 / 44775901
disulfoton	32501	106992 / 42755801	106332 / 42977401
fenamiphos	100601	107156 / 44041501	107434 / 44051401
fenthion	53301	107649 / 44326401	107764 / 44339401
methamidophos	101201	105053 / 43025001 105053-1 / 43345801 105053-2 / 43916201	106351 / 43197901
phostebupirim	129086	106804 / 43473001	106866 / 43656302
tribuphos	74801	in progress	in progress
trichlorfon	57901	107451 / 44578001	107153 / 43871701

To our knowledge, all of the completed studies have been favorably reviewed, so that the only requirements outstanding are the Developmental Neurotoxicity Studies requested in this DCI. A protocol for one of the subject chemicals, tribuphos, has already been submitted for Agency review, and it is BAYER's understanding that the protocol should be acceptable.

BAYER understands that efforts are proceeding to resolve certain technical questions regarding the

protocol for the Developmental Neurotoxicity Study as modified by the Data Call-in. Provided these discussions successfully resolve those issues, we agree to submit needed studies pursuant to mutually-agreed protocols. This commitment does not waive rights we may have to question or object to the DCI or its terms.

To clarify scheduling of all the requested studies, BAYER proposes to meet with the Agency around the beginning of February to discuss a possible staggered schedule for submission, similar to that which was worked out favorably with the Agency for the already submitted acute and subchronic neurotox studies. Please contact me as to an appropriate time when that can be accomplished.

As always, if you have any questions concerning this submission, please contact Dr. James Kunstman of my staff at (816) 242-2838.

Sincerely,
Bayer Corporation
Agriculture Division

James L. Kunstman for JST

John S. Thornton
Director, Product Registrations
and Regulatory Affairs

United States Department of the Interior

FISH AND WILDLIFE SERVICE

J.N. "Ding" Darling National Wildlife Refuge
1 Wildlife Drive
Sanibel, Florida 33957

January 11, 2001

Mr. George Wichterman, Entomologist
Lee County Mosquito Control District
PO Box 60005
FT Myers, FL. 33906

Dear Mr. Wichterman:

By means of this letter, I am clarifying an issue that was discussed by several representatives from the Environmental Protection Agency, Lee County Mosquito Control District (LCMCD) and myself on September 6, 2000. The subject of bird mortality due to adulticiding operations by LCMCD became a point of discussion. As I stated that day, by written agreement with LCMCD, the Refuge has not allowed adulticide operations on the Refuge since the mid 1980's. We have been very clear on this issue; and in order to insure compliance, four apiaries have been placed along the refuge's southern boundary. These areas would be the first to be impacted by incidental pesticide drift during LCMCD aerial operations. The bees function as the refuge's "canary" detection system.

During my tenure, the refuge has never experienced a bee mortality event and, more importantly, never endured a bird mortality event due to pesticides. Refuge staff and volunteers patrol Wildlife Drive every day, an area where high numbers of birds congregate. If birds were dying, for any reason, our staff and volunteers would find them.

I hope this clarifies my comments made in September.

Sincerely yours,

Louis Hinds

Louis S. Hinds III
Refuge Manager